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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/760,091	01/16/2004	Thomas L. Cantor	532212000624	2110

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MORRISON & FOERSTER LLP  
12531 HIGH BLUFF DRIVE  
SUITE 100  
SAN DIEGO, CA 92130-2040

EXAMINER

CHEU, CHANGHWA J

ART UNIT PAPER NUMBER

1641

MAIL DATE DELIVERY MODE

06/15/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

### Application No.

10/760,091

### Applicant(s)

CANTOR ET AL.

### Examiner

Jacob Cheu

### Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 47-71, 78-84, 86, 92, 93 and 95-107 is/are pending in the application.
- 4a) Of the above claim(s) 47-68 and 98-107 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 69, 71, 78-84, 86, 92, 93 and 95-97 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/4/07</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicant's amendment and Rule 1.132 affidavits filed on 3/23/2007 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 1-46, 72-77, 85, 87-91, 94, cancelled.
2. Currently, claims 69, 71, 78-84, 86, 92-93, 95-97 are under examination. Claims 47-68 and 98-107 are withdrawn from further consideration.

### ***Specification***

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

The instant claims recites an antibody recognizes a bioactive, three-dimensional epitope of a parathyroid hormone PTH. However, no disclosure of any bioactive, three-dimensional epitope is found in the specification.

### ***Double Patenting***

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

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*Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 69-71, 78-84, 92-93 and 95-97 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 20, 22, 38, 46 and 48 of Reexam No. 90007732 (US patent 6689566). Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions are drawn to an isolated antibody and the antibody isolated are capable of recognizing an initial PTH sequence and specifically bound to the whole PTH while avoiding binding to a non-(1-84) PTH fragment. The antibodies isolated from both applications are the SAME, albeit with a slightly different recitations of characteristics.

### ***Claim Rejections - 35 USC § 112***

#### ***New Matter***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 69, 71, 78-84, 86, 92-93, 95-97 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one

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skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

***“three-dimensional epitope within a PTH fragment”***

It is noted that the instant claim recites “an antibody binds to a bioactive, three-dimensional epitope of a parathyroid hormone (PTH), wherein said isolated antibody binds to said three-dimensional epitope within a whole PTH with a higher affinity than its binding to said three-dimensional epitope within a PTH fragment”. No support from the specification can be found. Although applicant in the Remarks indicates the inherent characteristics of the antibody, particularly at page 8, line 24-25 and Figure 11, however no “three-dimensional” epitope PTH fragment was never discussed in the whole specification (See Remarks page 13, fourth paragraph). Furthermore, applicant also submitted Dr. Lerner’s binding analysis in support of the assertion with respect to the newly amended claims. Surap (See Exhibit B). Examiner acknowledges the experimental data provided by Dr. Lerner as “inherent” properties of the instant antibody. Nonetheless, the newly amended claims lack support from the original specification, particularly with the term “three-dimensional epitope” PTH fragment. It is a new matter. The application belongs to “Continuation-in-Part”, not “Continuation” from its parent case (US PAT 6,743,590).

***non-(1-86) PTH fragment***

No support for the non-(1-86) PTH fragment is disclosed either from this application, or from its CIP US Patent 6689566. Applicant mentions in the Remarks that the support can be found at page 8, line 24-25 and Figure 11. However, the support from the above mentioned specification disclosing only non-(1-84) PTH fragment. Furthermore, the sequence data disclosed by applicant also show (1-84) PTH, not (1-86) PTH (See Sequence list).

***Response to Applicant's Arguments***

1. Applicant's arguments with respect to claims 69, 71, 78-84, 86, 92-93, 95-97 have been considered but are moot in view of the new ground(s) of rejection.
2. The rejections under Fisher et al. are withdrawn because the antibodies made by Fisher et al. do not have the property to recognize only whole PTH while not to bind to a non-(1-84) PTH fragment and binding affinity to the whole PTH are lesser than PTH fragment (See Dr. Lener's Exhibit D).
3. The rejections under Magerlein et al. (I) and (II) are withdrawn because Magerlein et al. did not use whole PTH molecule for immunization, rather Magerlein et al. merely use a short peptide 1-10 to immunize rabbit and collect antibodies. In contrast, the instant invention use whole PTH to immunize animals and isolate with a second PTH fragment, e.g. 1-8 or 1-9, and then verify that the isolated antibody would not bind to non- (1-84) PTH but bind to whole PTH.
4. The rejection under Colfor et al. are withwan because the antibodies made by Colford et al. do not posses the property of not recognizing the non-(1-84) PTH.
5. Accordingly, the 35 USC 103 (a) rejections are withdrawn based on the reasons mentioned above.

***Conclusion***

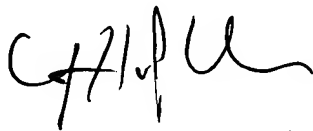
6. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'C. H. Cheu'.

Jacob Cheu

Examiner

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June 8, 2007